

DEPARTMENT OF HEALTH AND HUMAN SERVICES ^{DMB}

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Food and Drug Administration

21 CFR Part 884

[Docket No. 99N-0922]

Obstetric and Gynecology Devices; Effective Date of Requirement for Premarket Approval for Glans Sheath Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to require the filing of a premarket approval application (PMA) or a notice of completion of product development protocol (PDP) for glans sheath medical devices. The agency has previously published its findings regarding the degree of risk of illness or injury designed to be eliminated or reduced by requiring the devices to meet the statute's approval requirements and the benefits to the public from the use of the devices.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Colin M. Pollard, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1180.

SUPPLEMENTARY INFORMATION:

I. Background

Section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c) requires the classification of medical devices into one of three regulatory classes: Class I (general controls), class II (special controls), and class III (premarket approval). In the **Federal Register** of December
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29, 1994 (59 FR 67185), FDA issued a final rule classifying glans sheath devices into class III. Section 515(b)(1) of the act (21 U.S.C. 360e(b)(1)) establishes the requirement that the Secretary of Health and Human Services issue a regulation subjecting a preamendments device that FDA has classified into class III to premarket approval.

In the **Federal Register** of May 10, 1999 (64 FR 24967), FDA issued a proposed rule to require the filing of a PMA or a notice of completion of a PDP for glans sheath devices. In accordance with section 515(b)(2)(A) of the act, FDA included in the preamble to the proposed rule the agency's proposed findings regarding the degree of risk of illness or injury intended to be eliminated or reduced by requiring the device to meet the statute's approval requirements as well as the benefits to the public from use of the device.

The May 10, 1999, proposed rule also provided an opportunity for interested persons to submit comments on the proposed rule and the agency's proposed findings. In accordance with section 515(b)(2)(A) of the act, FDA also provided an opportunity for interested persons to request a change in the classification of the device based on new information relevant to its classification. Any petition requesting a change in the classification of the devices was required to be submitted by May 26, 1999. The comment period closed August 9, 1999.

FDA received no petitions requesting a change in the classification of glans sheath devices. FDA received no comments on the proposed rule.

II. Findings With Respect to Risks and Benefits

Under section 515(b)(3) of the act, FDA is adopting the findings as published in the proposed rule of May 10, 1999. As required by section 515(b) of the act, FDA published its findings regarding: (1) The degree of risk of illness or injury designed to be eliminated or reduced by requiring that these devices have an approved PMA or a declared completed PDP, and (2) the benefits to the public from the use of the device.

These findings are based on the reports and recommendations of the Obstetrics and Gynecology Devices Panel, an FDA advisory committee for the classification of the devices as referenced in the May 10, 1999, proposed rule.

III. The Final Rule

Under section 515(b)(3) of the act, FDA adopts the findings as published in the preamble to the proposed rule and issues this final rule to require premarket approval of glans sheath devices. This final rule revises part 884 (21 CFR part 884).

Under the final rule, a PMA or a notice of completion of a PDP is required to be filed on or before [*insert date 90 days after date of publication in the Federal Register*], for any glans sheath device that was in commercial distribution before May 28, 1976, or that has been found by FDA to be substantially equivalent to such a device on or before [*insert date 90 days after date of publication in the Federal Register*]. If a PMA or notice of completion of a PDP is filed for such devices within this time limit, the applicant will be permitted to continue marketing its glans sheath device during FDA's review of its submission. Any other glans sheath device that was not in commercial distribution before May 28, 1976, is required to have an approved PMA or a declared completed PDP in effect before it may be marketed.

If a PMA or a notice of completion of a PDP for a glans sheath device is not filed on or before [*insert date 90 days after date of publication in the Federal Register*], that device is deemed adulterated under section 501(f)(1)(A) of the act (21 U.S.C. 351(f)(1)(A)), and commercial distribution of the device must cease immediately. The device may, however, be distributed for investigational use, if the requirements of the investigational device exemption (IDE) regulations (part 812 (21 CFR part 812)) are met. Because the intended use of a glans sheath device is contraception, FDA considers it to be a significant risk device as defined in the IDE regulations (§ 812.3(m)(4)).

As of [*insert date 90 days after date of publication in the Federal Register*], the exemptions in § 812.2(c)(1) and (c)(2) from the requirements of the IDE regulations for preamendments class

III devices cease to apply to any glans sheath device that is: (1) Not legally on the market on or before *[insert date 90 days after date of publication in the Federal Register]*; or (2) legally on the market by *[insert date 90 days after date of publication in the Federal Register]*, but for which a PMA or notice of completion of a PDP is not filed by *[insert date 90 days after date of publication in the Federal Register]*, or for which PMA approval has been denied or withdrawn. FDA cautions that manufacturers who are not immediately planning to submit a PMA or notice of completion of a PDP should submit IDE applications to FDA by *[insert date 60 days after date of publication in the Federal Register]*, to minimize the possibility of interrupting shipment of the device. At this time, FDA is not aware of any firm that is marketing this device.

IV. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the final rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize

any significant impact of a rule on small entities. FDA has reviewed the situation and believes that no PMAs will be submitted under this final rule. FDA is not aware of any marketing of these devices at present. FDA has not received any premarket submissions for glans sheath devices in more than 15 years. Consequently, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 (Public Law 104-4) requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million in any one year (adjusted annually for inflation). The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for the final rule, because the final rule is not expected to result in any 1-year expenditure that would exceed \$100 million adjusted for inflation.

VI. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA). The burden hours required for § 884.5320(c), included in the collection entitled "Premarket Approval of Medical Devices—21 CFR Part 814," (64 FR 4112, January 27, 1999) are reported and approved under OMB control number 0910-0231. Therefore, clearance by OMB under the PRA is not required.

VII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

List of Subjects in 21 CFR Part 884

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 884 is amended as follows:

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

1. The authority citation for 21 CFR part 884 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 884.5320 is amended by revising paragraph (c) to read as follows:

§ 884.5320 Glans sheath.

* * * * *

(c) *Date premarket approval application (PMA) or notice of completion of a product development protocol (PDP) is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before *[insert date 90 days after date of publication in the Federal Register]*, for any glans sheath that was in commercial distribution

before May 28, 1976, or that has, on or before [insert date 90 days after date of publication in the Federal Register], been found to be substantially equivalent to a glans sheath that was in commercial distribution before May 28, 1976. Any other glans sheath shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

Dated: 5/14/02

May 14, 2002.

Linda S. Kahan

Linda S. Kahan,
Deputy Director,
Center for Devices and Radiological Health.

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